comprising

The polypeptide of claim 21, wherein said fragment comprises an amino acid sequence selected from the group consisting of SEQ ID Nos. 🛨 26-30 and 32-33 \[1-11 and 26-33]

REMARKS

Applicants wish to thank Examiner Huff for the courtesy extended to their representative during a telephone interview on February 9, 1994. Applicants found this interview helpful in clarifying the issues raised in the pending office action.

Claims 18-22 are pending in the application. Claims 18 and 22 have been amended to recite applicants' invention more clearly. The amendments presented address formal concerns raised by the examiner in the Final Office Action and place the claims in better form for consideration on appeal. No new matter is introduced by these amendments, and no new issues are raised by them. Accordingly, applicants respectfully request entry of the amendments and reconsideration of the claims.

Rejections Under 35 USC §112

. The examiner has objected to the specification for failing to enable a method for using the claimed invention as a therapeutic agent. While the examiner recognizes that the specification enables the use of the present invention as a diagnostic agent, she objects to the specification under 35 USC § 112, first paragraph, "in relation to the treatment of cancer" (Action at page 3). Applicants respectfully traverse this rejection on the grounds that it is improper.

Applicants are not aware of any statute or rule that allows the examiner to object to the specification under 35 USC § 112 without making a corresponding rejection of one or more claims. In this regard, Examiner Huff indicated during the telephone

interview that she interpreted the "enablement" requirement of § 112 to apply to all possible uses disclosed in the specification because she interpreted the term "the invention" to encompass all embodiments and applications disclosed in the specification, not just those recited in and encompassed by the claims.

Applicants respectfully point out, however, that all of the requirements of § 112 apply to the <u>claimed</u> invention. In re Vogel 422 F.2d 438, 441, 164 USPQ 619, 621 (CCPA 1970); In re Tanczyn 347 F.29 830, 832, 146 USPQ 298, 300 (CCPA 1965). This interpretation is consistent with the second paragraph of § 112, which states that the <u>claims</u> must particularly point out what applicant believes to be his <u>invention</u>. Because the claims set forth the only definition of the invention, it is the <u>claims</u> that must be enabled by the specification. Because the instant specification fully meets the requirements of the first paragraph of § 112 with respect to the <u>claimed</u> invention, applicants respectfully request that this rejection be reconsidered and withdrawn.

Claim 22 is rejected, and the specification is objected to, under the first paragraph of § 112 for an alleged lack of written description with regard to the amino acid sequences which comprise amino acids designated as "X". Applicants maintain that these sequence are sufficiently described in the specification, and that the knowledgeable reader would understand that these potentially glycosylated amino acids are most likely Asp, Thr, or Ser. In order to expedite prosecution, however, applicants have amended claim 22 so that it no longer recites amino acid sequences which comprise amino acids designated as "X". Applicants therefore believe that this rejection has been obviated.

Claim 22 is rejected and the specification is objected to again under the first paragraph of § 112 for an alleged lack of "enablement," and under the second paragraph of § 112 for "indefiniteness," because of the use of the "open" terms "comprising" or "containing." In an effort to resolve this issue, applicants conducted a telephone interview with Examiner Huff on February 9, 1994. While no final agreement was made during this interview, Examiner Huff suggested that we address the statement at page 5 of the action that it is "unclear if applicant intends to limit the fragment to the specific sequences."

Applicants wish to clarify for the record that they indeed intend the <u>open</u> language of the claim. That is, applicants wish to claim a fragment of human autotaxin protein which comprises any of SEQ ID NOS 1-4, 6-11, 26-30 and 32-33. The fragment may consist of one of these sequences alone, or it may consist of one of these sequences together with other amino acids.

With regard to the statement at page 4 of the action, to the effect that the rest of the compound encompassed by the open language is "unduly broad," applicants respectfully point out that the scope of the claimed fragments is qualified by claim 18, which requires that "antibody suitable for immunohistochemical staining can be raised to" the fragments. These fragments thus are defined and adequately delimited by the claim language itself.

Page 4 of the action also states that applicants "have not enabled a method of making fragments that contain" the recited sequences. Applicants respectfully traverse this rejection. It is well within the level of ordinary skill in the art to synthesize de novo fragments of the length of the recited sequences. It is further within the level of ordinary skill in the art to link these fragments to other amino acids, peptides

or proteins, thereby to make a fragment "comprising" the recited sequence together with additional amino acid residues. Alternatively, based on the teachings set forth in the specification, one could isolate autotaxin and digest the protein to obtain shorter fragments of the protein (see, e.g., page 22 of the specification), or one could produce the fragments recombinantly, as described at pages 12-13 of the specification.

Applicants assert, therefore, that the fragments of claim 22 are fully described and enabled by the teachings of the specification, and respectfully request that this rejection be reconsidered and withdrawn.

Claims 18-22 are rejected under 35 USC § 112, second paragraph, as being indefinite in the language of paragraph (B). Applicants have amended claim 18 to recite that antibodies can be raised to the protein and fragments of the invention. Applicants therefore believe that this rejection has been overcome.

Conclusion

In view of the foregoing amendments and remarks, this application is believed to be in condition for allowance, and an early indication of the same is respectfully requested. If Examiner Huff has any further questions regarding this application, she is invited to contact the undersigned attorney at the number shown below.

It is believed that no additional fees are required; however, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-0741.

It is further believed that no additional petition for an extension of time under 37 C.F.R. § 1.136 is required. However, should such a petition be required, applicant hereby petitions the Commissioner for an extension of time, and authorizes the Commissioner to charge the necessary petition fee to Deposit Account No. 19-0741.

Respectfully submitted,

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